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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,230	05/08/2001	John Hamilton	E1679-00007	4015
42109	7590	10/05/2006	EXAMINER	
DUANE MORRIS LLP PATENT DEPARTMENT 380 LEXINGTON AVENUE NEW YORK, NY 10168-0002			BELYAVSKYI, MICHAEL A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,230	HAMILTON ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskiy	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/19/06 has been entered.

2. Claims 29-34 are pending and under consideration in the instant application.

3. Applicant's submission of Declaration by Dr. Hamilton and Dr. Anderson under 37 C.F.R. 1.131 is acknowledge. Said Declaration indicated that the claimed subject matter was invented and reduced to practice prior to March 20, 2000.

It is noted that if Applicant intended to suggest interference under 37 CFR 41.202, then Applicant must follow the procedure required by MPEP, section 2304.02.

In view of the applicant's arguments filed on 07/19/06 the following rejections remain:

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

5. Claims 29-33 stand rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0141994A1 for the same reasons set forth in the previous Office Action, mailed on 03/28/06.

Applicant's arguments, filed 07/19/06 have been fully considered, but have not been found convincing.

Applicant asserts that US '994 publication is only entitled to an effective filing of February 23, 2001. Claiming priority to March 20, 2000 was impermissible and thus US '994 publication does not constitute a proper prior art under 35 U.S.C. 102(e).

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Contrary to Applicant's assertion, a petition to convert a provisional application to non-provisional was timely filed within one year of filing a **second provisional application**, filed on February 23, 2001, thus is entitled to claim an effective filing day of first provisional application, filed on March 20, 2000. Accordingly, an effective filing day of US '994 publication is March 20, 2000 and thus **does constitute** a proper prior art under 35 U.S.C. 102(e)

US Patent '994, teaches a method for ameliorating the effects of inflammation in a subject, comprising administering antibody specific for M-CSF (see entire document, page 2, paragraphs 22-24, page 3, paragraph 26 and page 6, paragraph 86 in particular). US Patent '994 teaches that administering of said antibody inhibit the effect of M-CSF on monocytes/macrophages (see column 6, paragraph 93 in particular).

Claims 30 and 33 are included because the claimed functional limitation would be inherent properties of the referenced antibodies against GM-CSF, because the claimed method for ameliorating the effects of inflammation and the referenced method using the same antibodies against GM-CSF. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The reference teaching anticipates the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 29, 30 and 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0141994A1 in view of US Patent 5444153 or US Patent 5662609 for the same reasons set forth in the previous Office Action, mailed on 08/10/05.

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Applicant's arguments, filed 02/10/06 have been fully considered, but have not been found convincing.

Applicant asserts that since US '994 is not a valid reference against the present application, it cannot be used for 103 (a) rejection.

As has been discussed, supra, it is the Examiner position that US'994 publication is a valid reference and can be used for 103 (a) rejection.

The claimed invention differs from the reference teaching in that the US 2002/0141994A1 does not teach a method for ameliorating the effects of inflammation in a subject comprising administering antibodies against M-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

US Patent '153 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA (see entire document, Abstract column 2 and column 5, lines 55-65, and column 6 in particular).

US Patent '609 teaches a method of treating inflammatory diseases in patients comprising administering specific inhibitors of u-PA or inhibitors of agents which inhibits the effects of inflammatory mediators (see entire document, column 4 and column 6 in particular).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of US Patent '153 or US Patent '609 to those of US 2002/0141994A1 to obtain a claimed method for ameliorating the effects of inflammation in a subject comprising administering antibodies against M-CSF and further administering an agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because agent which antagonizes the effects of u-PA and an agent which antagonizes the effects of other inflammatory mediators can be used in the a method of treating inflammatory diseases as taught by US Patent '153 or US Patent '609 and can be combined with a method of treating inflammatory diseases in patients taught by WO 00/09561 or JP 2000198799 or US Patent 5,837,460. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles

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or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

8/29/06